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Original article

Clinical and radiological outcomes with the Durom™ acetabular cup for large-diameter total hip arthroplasty: 177 implants after a mean of 80 months

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ABSTRACT

Background: Large-diameter metal-on-metal hip prostheses are no longer used, but their outcomes after more than 5 years are unknown. We conducted a retrospective study with a 6.8-year mean follow-up to assess clinical outcomes after Durom™ cup implantation, including the dislocation rate, comparatively to the reference metal-on-polyethylene bearing. We determined the rate of failure ascribable to Durom™ cup use. We also looked for a sharp drop in the implant survival curve during the follow-up period and for factors associated with adverse reactions to metal debris (ARMDs).
Hypothesis: We hypothesised that clinical outcomes after Durom™ cup implantation were similar to those seen with a metal-on-polyethylene bearing, except for a lower rate of dislocation.
Patients and methods: We included 177 consecutive THA procedures that were performed between 2005 and 2008 in 165 patients with a mean age of 57.6 ± 9.4 years (range, 31–76 years) and involved the implantation of a Durom™ cup, a femoral head greater than 36 mm in diameter, and a PF® femoral stem (Zimmer, Etupes, France). The mini-posterior approach was used, with 2 mm of acetabular overreaming in 82% of cases, a short femoral neck in 75% of cases, and a mean cup inclination of 34 ± 5° (range, 21–50°).
Results: Outcomes were assessed for 156 THA procedures in 146 patients after a mean follow-up of 6 years 8 months. The mean Postel-Merle d'Aubigné score improved from 9.7 ± 2.7 (range, 4–14) to 17.4 ± 1.7 (range, 15–18) and the mean Harris hip score from 45.2 ± 15.3 (range, 9–83) to 96.3 ± 7 (75–100). No episodes of dislocation were recorded. We identified 7 failures ascribable to the Durom™ cup including 6 due to ARMD and 1 to aseptic loosening. Implant survival after a mean of 80 months was 95.5% (95% CI, 93.1–99.2), with no sharp drop in the survival curve.
Conclusion: The Durom™ cup eliminates the risk of hip dislocation and produces similar functional outcomes to those seen with metal-on-polyethylene bearings after a mean follow-up of 80 months. Nevertheless, given the difficulty in predicting ARMD and hypersensitivity reactions, the Durom™ cup has been discarded and patients carrying it are monitored closely.
Level of evidence: IV, retrospective study.

1. Introduction

Although recently described in *The Lancet* as the surgical operation of the century [1], total hip arthroplasty (THA) still raises a number of challenges such as increasing implant survival and diminishing postoperative complications, most notably in young patients. Efforts to meet these challenges have included the re-introduction of metal-on-metal implants with large-diameter femoral heads and cups capable of accommodating them, such as the Durom™ cup (Zimmer, Étupes, France) (Fig. 1). In theory, this strategy should decrease the risk of wear and dislocation [2].

Recent analyses of national registry data [3,4], however, showed high failure rates with large-diameter metal-on-metal implants. The events responsible for failure included classical complications (early loosening) and specific complications (adverse reactions to metal debris [ARMDs]). In 2013, French health authorities recommended discarding large-diameter metal-on-metal implants.

At our institution, the Durom™ cup was used between 2005 and 2009. We hypothesised that clinical outcomes with this cup compared favourably to those of the reference metal-on-polyethylene

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Fig. 1. The Durom™ cup is a truncated hemisphere with fins around the equator

bearing, with a lower dislocation rate. No data have been published on outcomes after more than 5 years. We therefore conducted a retrospective study of 177 Durom™ cup implantations evaluated after at least 6 years. We assessed clinical outcomes, including the dislocation rate, comparatively to the reference metal-on-polyethylene bearing, as well as the rate of failure ascribable to Durom™ cup use. We also looked for a sharp drop in the implant survival curve during the follow-up period and for factors associated with ARMDs.

2. Patients and methods

2.1. Patients

We retrospectively evaluated consecutive cases of primary THA performed at a single centre and by a single surgeon between August 2005 and August 2008. Inclusion criteria were age younger than 70 years (170 hips) or age 70 years or over with a Devane activity grade of 4/5 or risk factors for premature wear (obesity and/or strenuous physical activities) ($n = 7$ hips). We excluded women of childbearing age and patients with major acetabular dysplasia. Table 1 lists the main features of the 165 included patients (177 THA procedures). A history of allergic manifestations or atopy was sought routinely during the preoperative patient interview from 2006 onwards but, at the time, was not considered a contraindication to the use of large-diameter metal-on-metal prostheses.

2.2. Operative procedure

The same surgeon (DS) performed all THA procedures, via a mini-postero-lateral approach with preservation of the piriformis muscle. During the early part of the study period, the acetabulum was prepared using a same-size hemispheric reamer to allow press-fit impaction of the cup, as recommended by the manufacturer. However, some imaging studies showed absence of close contact between the acetabular bone and cup, and overreaming by 1 to 2 mm was therefore rapidly introduced. This method produced exact-fit conditions, as the cup was larger than the recommended reamed cavity. Of the 177 acetabula, 21 (12%) were prepared using a same-size reamer, 10 (6%) were overreamed by 1 mm, and 146 (82%) were overreamed by 2 mm.

Cup diameters ranged from 44 to 62 mm and femoral head diameters from 38 to 56 mm. Given the good stability obtained with large-diameter heads, the surgeon gave preference to short femoral necks ($n = 133$, 75%); medium-length necks were used in 40 (23%) cases and long necks in only 4 (2%) cases.

For all 177 procedures, a PF™ femoral stem (Zimmer, Etupes, France) was chosen. In 165 (93%) cases, an uncemented titanium stem whose proximal part was coated with hydroxyapatite was implanted. In the remaining 12 (7%) cases, poor primary holding power or an intra-operative fracture of the calcar prompted the use of a cemented high-nitrogen stainless steel stem. A standard stem was used in 74 (42%) cases and a lateralised stem in 103 (58%) cases.

Table 1
Main features of the 165 included patients.

Features	Values
Number of patients	165
Number of THA procedures	177
Males, n	88 (95 THAs)
Females, n	77 (82 THAs)
Age, mean ± SD (range)	57.6 ± 9.4 years (31 to 76 years)
Right hip/Left hip (Both hips), n	79/74 (12)
Body mass index	27.6 ± 5.4 kg/m^2 (16 to 50)
Body mass index > 30 kg/m^2	37 (21%)
Hip osteoarthritis, n (%)	147 (83%)
Idiopathic hip osteoarthritis	128
Moderate dysplasia	11
Acetabular protrusion	4
Post-traumatic hip osteoarthritis	4
Avascular femoral head necrosis	30 (17%)
Idiopathic, *n*	21
Post-traumatic, *n*	8
Post-septic arthritis, *n*	1
Previous surgery on the hip, n	20 (11%)
Devane activity scale [5] (grades 1 to 5), n	1, $n = 8$; 2, $n = 91$; 3, $n = 63$; 4, $n = 3$

2.3. Assessment methods

A clinical evaluation was performed more than 6 years after the THA procedure in 146 patients (156 THAs), either by the surgeon ($n = 49$, 31%) or by another observer ($n = 107$, 69%), who called up the patients when the medical record was incomplete (less than 6 years' follow-up). To assess functional outcomes, we determined the Postel-Merle d'Aubigné (PMA) score [6], Harris hip score [7], and Devane activity score [5]. Subjective patient satisfaction was assessed using a five-grade system: very satisfied, satisfied, neither satisfied nor dissatisfied, dissatisfied, and very dissatisfied.

Antero-posterior and lateral radiographs of the hip were obtained, as well as a standing antero-posterior pelvic radiograph, to assess cup position and integration. Cup inclination was measured relative to the radiological tear-drop. Peri-prosthetic lucent lines and sclerotic foci were recorded and each of these abnormalities was mapped to the topographic areas defined by DeLee and Charnley [8].

Routine ultrasonography was performed in patients with unexplained pain, osteolysis, or bone cysts ($n = 19$) to look for a significant joint effusion (> 10 mL) or for a mass within the joint cavity or around the prosthesis. When the ultrasonography findings were consistent with the clinical symptoms (pain) and radiological findings (osteolytic foci), revision surgery was considered. A minority of patients underwent whole-blood chromium and cobalt ion assays [9] ($n = 3$) or technetium 99 scintigraphy ($n = 5$) to further support the diagnosis before revision surgery.

Table 2
Clinical outcomes of total hip arthroplasty (THA) with the Durom™ cup.

	Before THA 165 patients 177 hips	At last follow-up 146 patients 156 hips
Postel-Merle d'Aubigné score [6], mean ± SD (range)	9.7 ± 2.7 (4–14)	17.4 ± 1.7 (15–18)
Postel-Merle d'Aubigné score > 16, *n* (%)		148 (94.9%)
Harris hip score [7], mean ± SD (range)	45.2 ± 15.3 (9–83)	96.3 ± 7 (75–100)
Harris hip score > 80, *n* (%)		149 (95.6%)
Devane activity grade, mean ± SD (range)	2.37 ± 0.6 (2–4)	3.7 ± 0.7 (2–5)

ARMD was documented histologically by determining the 10-point aseptic lymphocytic vasculitis-associated lesion (ALVAL) score [10].

2.4. Statistical methods

Statistical analyses were performed using XLStats™ software (Addinsoft, Paris, France). Student's *t* test was chosen to compare quantitative variables, with p values ≤ 0.05 considered significant. Implant survival was assessed using the Kaplan-Meier method with computation of the 95% confidence intervals (95% CIs); two end-points were used, revision for any reason and revision for reasons other than infection.

3. Results

Of the 165 patients, 9 (5.6%) died for reasons unrelated to THA (including 1 with bilateral THA) and 10 (6.2%) were lost to follow-up (including 1 with bilateral THA), leaving 146 patients and 156 THA procedures for the analysis. The follow-up rate was 88.1% and mean follow-up was 80 ± 11.6 months (range, 72–104 months), i.e., 6 years 8 months.

No cases of hip dislocation or subluxation were recorded. Table 2 recapitulates the objective clinical outcomes. Patient satisfaction outcomes were distributed as follows: very satisfied or satisfied, $n = 132$ (90.4%); neither satisfied nor dissatisfied, $n = 9$ (6.2%); and dissatisfied, $n = 5$ (3.4%).

Mean cup inclination was 34.1 ± 5.1° (range, 21–50°). A single cup had more than 45° of inclination. Osteolysis or a cyst was visible in the acetabular bone in 9 (5.8%); the lesion involved zone 1 in 7 hips and zones 1 and 2 in 2 hips. A peri-acetabular lucent line was seen for 6 implants: 3 were in zone 1, 2 in zone 2, and 1 in zone 3.

Of the 146 patients, 15 (10.3%) reported chronic groin pain and therefore underwent ultrasonography. This investigation showed a significant intra-articular effusion (> 10 mL) in 6 hips (5 patients), all of which exhibited osteolysis, located in the acetabular fossa ($n = 4$) or calcar ($n = 2$). In 3/6 cases, whole-blood ion assays were performed; the results further supported ARMD (blood cobalt > 7 μg/L). All 6 hips (in 5 patients) were managed by revision surgery to change the bearing couple by implanting a dual-mobility cup. A serous cyst was found intra-operatively in all 6 hips, suggesting ALVAL, as well as chalky material in 2 cases and metallosis in 2 cases. The histological results confirmed ARMD as the cause of cup failure (Table 3). The remaining 9 patients with chronic groin pain reported only moderate discomfort and were therefore managed by close monitoring without revision surgery.

Cup loosening occurred in 1 patient, whose implant migrated after 34 months due to collapse of an osteoarthritic cyst present preoperatively and not grafted during the primary THA procedure.

In all, 7 cup failures were ascribable to the Durom™ cup, in 6 patients, 4 females and 2 males including 1 with bilateral THA (Table 3). When surgical revision for any reason related to the cup (aseptic loosening or bearing couple failure) was the endpoint, cup survival after the mean 80-month follow-up was 95.5% (95% confidence interval [95% CI], 93.1–99.2).

Extra-acetabular complications included one peri-prosthetic femoral fracture on day 8 after a fall on stairs and one early loosening of an uncemented femoral stem after 9 months, which were managed by revision surgery for stem replacement. Four patients experienced delayed infection presumed to be haematogenous and documented by multiple bacteriological specimens; they required exchange revision surgery.

Thus, after a mean follow-up of 80 months, when the endpoint was revision surgery for any reason except infection, the implant survival rate was 94.8% (95% CI, 90.9–98.8). Using revision surgery for any reason as the endpoint, the implant survival rate was 92.7% (95% CI, 87.9–97.5).

Table 3
Characteristics of the 7 cases of Durom™ cup failure.

Case	1	2	2bis	3	4	5	6
Sex	F	M	M	F	F	M	F
Age (years)	58	37	38	72	50	59	68
BMI, mean	32.9	24.8	24.8	32.7	32.5	31.2	30.5
Underlying disease	Hip OA	AVN	AVN	Hip OA	Hip OA	Hip OA	Hip OA
Allergies	Nickel	Hymenoptera venom	Hymenoptera venom	Pollens		Shellfish	
Overreaming (mm)	2	2	2	2	2	2	2
Head diameter (mm)	40	46	46	44	38	46	44
Neck	Standard	Short	Short	Short	Short	Standard	Short
Stem	Lateralised	Lateralised	Lateralised	Lateralised	Standard	Lateralised	Standard
Cemented stem	No	No	No	No	No	No	Yes
Cup inclination (°)	34	36	40	36	36	35	36
Radiographic findings	Osteolysis of calcar	Osteolysis of acetabulum	Osteolysis of acetabulum	Osteolysis of calcar and acetabulum	Osteolysis of calcar and acetabulum	Osteolysis of acetabulum	Cup migration
Effusion at ultrasonography	+	+	+	+	+	+	
Bone-scan	+			+	+	0	
Blood cobalt (μg/L)		High (11.7)	High (11.7)			High (15.2)	
Time to revision (months)	54	41	31	49	17	96	34
Cup fixation at revision	Firmly held	Firmly held	Firmly held	Loose	Loose	Firmly held	Loose
ALVAL 10-point histological score	8	9	9	9	8	9	1

ALVAL: aseptic lymphocytic vasculitis-associated lesion; OA: osteoarthritis; AVN: avascular necrosis.

Table 4
Comparison of clinical outcome scores obtained in published studies of Durom™ cup total hip arthroplasty.

Study	Number of hips	Follow-up (years)	Mean PMA score [6]	Mean Harris hip score [7]
Long et al. [11]	207	1.6		87
Illgen et al. [12]	63	1		89.7
Berton et al. [13]	100	3.6	17.3	93.9
Mertl et al. [14]	106	2,5	17	
Lardanchet et al. [15]	24	2	17.5	
Current study	156	6.8	17.4	96.3

PMA: Postel-Merle d'Aubigné.

Table 5
Comparison of clinical outcome scores in our study and in previously published studies of metal-on-polyethylene implants.

Study	Number of hips	Follow-up (years)	Mean PMA score [6]	% patients with PMA score > 16	Mean Harris hip score [7]	% patients with Harris hip score > 80
Wroblewski et al. [16]	71	6		96		96
Kerboull et al. [17]	286	10	17.2			
Hulleberg et al. [18]	138	13	15.1		83	83
Bjorgul et al. [19]	240	10			87.9	
Liang et al. [20]	77	6			96.5	
Mesnil et al. [21]	105	10	14.2			
Current study	156	6.8	17.4	95.6	96.3	94.9

PMA: Postel-Merle d'Aubigné.

4. Discussion

Our study provides information on survival of the large-diameter metal-on-metal Durom™ implant after a mean follow-up of 80 months. Clinical outcomes were good or excellent in 95.6% of cases according to the Harris hip score (mean, 96.3) and in 94.9% of cases according to the PMA score (mean, 17.4). These results are consistent with those reported previously for the same implant (Table 4) but were obtained after a longer mean follow-up [11–15].

The limitations of our study are inherent in the retrospective non-randomised design with no control group. After excluding the patients who died, the lost-to-follow-up rate was lower than 10%, in keeping with earlier studies. For our clinical and radiological study, whole-blood ion assays were not obtained routinely. Instead, they were performed as needed to assist in the diagnosis and follow-up of patients with chronic groin pain, as recommended by Hanneman et al. [9].

Overall, the clinical outcomes in our study were at least as good as those reported for metal-on-polyethylene implants with a femoral head diameter of 22.2 mm [16–21] (Table 5). In agreement with previously published studies of large-diameter metal-on-metal implants, none of our patients experienced hip dislocation. This advantage of using femoral heads measuring at least 36 mm in diameter has also been reported with other bearing couples such as ceramic-on-ceramic and metal-on-polyethylene [22].

Our 4.5% rate of failure due to the Durom™ cup is slightly lower than previously reported rates, which range from 0.8% to 31% (mean, 11%; median, 8.7%) after shorter mean follow-ups [11–15,22–25] (Table 6). With other cups, surgical revision is also required in some cases. A study by Bozic et al. [26] of 51,345 THA revisions before the introduction of large-diameter metal-on-metal implants showed that revision for cup replacement was required in over 30% of cases and was particularly common in the group aged 65 to 74 years. Delaunay et al. [27] reported that, among 2107 revisions within a mean follow-up of 11 years, 38.5% were performed only to replace the cup (dislocation, loosening, wear, or cup rupture). We previously conducted a preliminary study of the same population, in 2010, when mean follow-up was 38 months [28]. The rate of failure ascribable to the Durom™ cup was 2.7%, and chronic groin pain was reported in 4.5% of cases. Our data obtained after 80 months show a steady decline in survival over time with no sudden drop, in contradiction to results reported by Ng et al. [24] and Hutt et al. [25].

Table 6
Comparison of cup revision rates in published studies of Durom™ cup total hip arthroplasty.

Study	Number of hips	Follow-up (years)	Cup revision rate (%)
Long et al. [11]	207	1.6	15
Illgen et al. [12]	63	1	11.1
Berton et al. [13]	100	3.6	5
Ng et al. [24]	297	2	31
Lardanchet et al. [15]	24	2	8.3
Althuizen et al. [23]	64	3.1	9
Hutt et al. [25]	84	5	0.8
Current study	156	6.8	4.5

None of the factors assessed in our study was significantly associated with revision surgery or ARMD. However, the group with revision surgery had higher values for the proportion of women and mean body mass index compared to the remainder of the population. De Haan et al. [29] reported a predominance of females, and Bartelt et al. [30] younger age, among patients requiring revision surgery. Overreaming to obtain exact-fit conditions for cup implantation improved impaction of the equatorial fins into the bone and ensured closer contact between the acetabular fossa and the cup, thereby increasing primary holding power. Nevertheless, a consistent finding during revision surgery for cup replacement was poor secondary osteo-integration, and cup removal induced no loss of bone, as reported by others [31]. Cup inclination relative to the radiological tear-drop should be within the safe zone, defined as 30 to 45° [32]. Inclination greater than 45° results in edge-loading of the cup, which increases the shedding of metal debris and, therefore, the risk of a local inflammatory response. Mean cup inclination in our study was 34.1°, i.e., less than in earlier studies of the Durom™ cup: 48.6° for Mertl et al. [14], 41.3° for Long et al. [11], 50.9° for Lardanchet et al. [15], and 49.2° for Berton et al. [13].

Lavigne et al. [33] reported that the cobalt-chrome adapter sleeve of the Durom™ cup promoted corrosion at the junction with the titanium femoral stem, a problem not seen with titanium adapter sleeves (Magnum™ cup, Biomet, Warsaw, IN, USA). Metal-

losis was found in only 2 of the 7 revision procedures in our study, yielding a metallosis-related failure rate similar to that reported with the Magnum™ cup (1.6 to 2.7% with a 5-year follow-up). This low frequency of sleeve-stem corrosion may be ascribable to the use of short femoral necks in most of our patients (75%). Bishop et al. [34] demonstrated that long adapter sleeves increased asymmetrical loading of the morse taper junction, thereby promoting corrosion.

We found no association between patient-reported allergy to metals (nickel, chromium, cobalt) and bearing couple failure. Self-reporting may lack sensitivity, as only 3 (1.7%) of our patients described a history of metal allergy (ordinary jewellery, nickel, cobalt, or chromium). No reported studies have documented an increased risk of revision surgery among atopic patients.

5. Conclusion

The large diameter of the metal-on-metal Durom™ cup eliminates all risk of dislocation and produces highly satisfactory functional outcomes that compare favourably with those of the reference bearing couple. Nevertheless, the metal-on-metal bearing couple is associated with specific complications, and the development of ARMD is difficult to predict. Studies with longer follow-ups are needed to obtain accurate information on the long-term behaviour of these implants.

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